

Information Guide for Parents Raising a Child with a Disability

January 31, 2022



Introduction



This COVID-19 information guide was created to address vaccine hesitancy within the disability population.

In July 2021, we surveyed parents raising a child with a disability to see why they were hesitant about vaccinating themselves and their child or adult that they are the guardian of.

The survey results showed that 29% of parents who were willing to get vaccinated themselves were hesitant about vaccinating their child.

Many worried about vaccine ingredients, were unsure of how the new vaccines worked, and were unsure of short term and long term side-effects of the vaccine.

This document answers many of the questions that emerged from the vaccine hesitancy survey. The information found within this document was taken from peer reviewed journal articles, the CDC website, and the FDA.



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What is COVID-19?



COVID-19 is a virus but is not like the typical flu. In March 2020, the World Health Organization declared that COVID-19 was a global pandemic. A study comparing the COVID-19 cases between March 1 and April 30, 2020, and 5 previous flu seasons found that people who had COVID-19 were more likely to require ventilation (31 % vs. 8%) and more had a higher mortality rate once admitted to the hospital (20% vs. 3%). (Donnino, M. 2021)

In 2020, there was an increased mortality rate of 17.7% in the United States. 503, 976 more people died in 2020 compared to 2019. (Ahmad 2021)

What vaccines have been approved for COVID-19?

In the United States, there are currently 3 vaccines that have been granted Emergency Use Authorization (EUA) from the FDA. Those are Pfizer-BioNTech, Moderna, and Johnson & Johnson. All of these vaccines are given with a needle.

On August 23rd, 2021, Pfizer-BioNTech mRNA vaccine was given full approval by the FDA. On October 29th, 2021, Pfizer-BioNTech mRNA vaccine received a EUA for children 5-11.

Do the vaccines cost me money?

No. The vaccines are free.

Where can I get the COVID-19 vaccine?

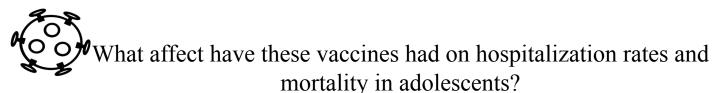
Find a vaccination location near you on this website: https://www.vaccines.gov/search/

Can I get a vaccine at home?

Yes! Call Spectrum Healthcare at 1-844-943-7387.

What affect have these vaccines had on hospitalization rates and mortality?

The Center for Disease Control (CDC) has stated that data from January to June 2021 in the U.S. suggested that 99.5% of COVID-19 deaths were unvaccinated people. A nationwide study conducted in Israel looking at the four months of their vaccination campaign showed that two doses of the Pfizer-BioNTech vaccine was 91% effective at preventing infection and 96% effective at preventing hospitalization and death (Hass 2021).



Researchers looked at hospitalization rates of children ages 12-17 between June 20 - July 31, 2021 an found that unvaccinated adolescents were 10.1 times more likely to be hospitalized for COVID-19 than their vaccinated peers. (Delhoy 2021)

What is the vaccine approval process?

Pre-Clinical Phase: Research is typically conducted on new vaccines in animals before they are tested on humans.

The vaccine approval process has 3 Phases in clinical development:

Phase 1: a small group of people receives the vaccine

Phase 2: a larger targeted population based on age and health take the vaccine

Phase 3: thousands of people are given the vaccine

Vaccines are given full approval after the Phase 3 trial is completed and has shown to be safe.

What steps were taken to ensure the safety of these vaccines?

Scientists followed the same steps taken for a typical vaccine approval process. However, a few steps were altered to accelerate the approval process.

Typically, the testing done on animals is done before the vaccine is tested on humans. For the COVID mRNA vaccine, these tests were performed at the same time. The second change was in the timeline for Phase 3 of the study. For an Emergency Use Authorization to be given, patients in the Phase 3 portion of the study must be followed for severe adverse side effects for at least two months. (apnews.com)

When the Pfizer-BioNTech vaccine was granted Emergency Use Authorization, over 35,000 people had participated in the clinical development process.

Pfizer-BioNTech, Moderna, and Johnson & Johnson are the first vaccines that have been granted Emergency Use Authorization.

On August 23rd, 2021, Pfizer-BioNTech mRNA vaccine was given full approval by the FDA.

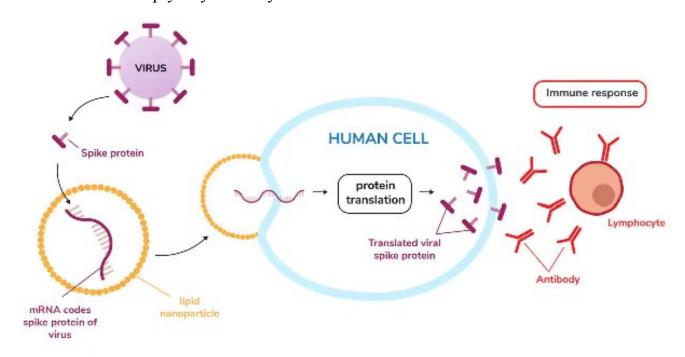
How do the COVID-19 mRNA vaccines work?



Pfizer-BioNTech and Moderna are mRNA vaccines.

The COVID-19 virus is round in shape and has projections that come off of its surface. These are called spike proteins. When your body encounters a foreign substance- like the COVID-19 virus, it produces an immune response to destroy that foreign substance.

The mRNA vaccine work by injecting people with the mRNA that contains instructions for the cell to produce the spike protein on the surface of the cells in their body that encounter the mRNA. The body's natural defense system will see those proteins as foreign substances and creates antibodies to destroy them. Those antibodies remain in your system and if your body encounters that spike protein again, it can recognize it quickly and mark it for destruction before it can multiply in your body.



Messenger RNA vaccines get the recipient's body to produce a viral protein that then stimulates the desired immune response. Trinset/IStock via Getty Images Plus

- mRNA is made up of different nucleotides: adenine (A), uracil (U), guanine (G), cytosine (C)
- mRNA is a short-lived molecule that creates specific proteins
- mRNA does not alter DNA- it never enters the nucleus
- mRNA does not cause infertility
- mRNA does not remain in your system for a long period of time- breaks down into its separate nucleotides within 20 hours- this is why the mRNA vaccine must be kept in such cold temperatures
- mRNA vaccine does not infect you with the COVID-19 virus



Is mRNA technology new?

Yes and no. mRNA technology has been around since 2010 and has been involved in Phase I, II, and III drug trials for various mRNA vaccines. The creation of and delivery of the mRNA vaccine from the needle and into the cell has been studied and experimented on for the past ten years. So even though we do not have any long-term studies on the COVID-19 vaccines, we do have long-term studies on similar mRNA vaccines, and those show positive longer-term safety outcomes.

If mRNA technology has been around for a few years, why is this the first time it has been used on a wide scale?

The reason comes down to two things: clinical trials and money.

To test a new vaccine it takes people willing to sign-up for clinical trials and it takes money.

It would also cost billions of dollars to alter the vaccination systems we have in place. The traditional vaccine industry has been in business for over 70 years. The complexes to support that type of vaccine production have been built and paid for. The vaccines produced traditionally cost less, are more stable at room temperature and have a proven track record.

To bring the mRNA vaccines to the marketplace on a massive scale, billions of dollars were required to develop that industry and allow for the transportation of the mRNA vaccines at low temperatures. (usatodaynews.com)

So why shift to mRNA?

mRNA is unique in that it takes several steps out of the vaccination production process. Traditional vaccinations require incubation in eggs. Then, the virus is put into the hen's eggs, and the eggs replicate the virus. The flu viruses are then killed and then purified. This process takes longer, has more steps than the mRNA vaccine, and therefore can have more errors during production. This process also takes a longer time to produce the vaccines; this is why scientists must guess every year which strain of the flu will be most prominent during flu season so they can make enough vaccines by the time the flu hits the United States.

The mRNA vaccine skips many of these steps by simply putting the blueprints for the spike protein directly into your cell. This means that as soon as scientists know what the blueprints are (mRNA sequence), they can immediately create a vaccine for it. According to Walter Isaacson's book *The Code Breaker*, it took Moderna 2 days to make the RNA sequence and only 38 days to ship off its first vials of the vaccine.

How does the Johnson & Johnson/ Janssen vaccine work?



Johnson & Johnson/Janssen is a viral vector vaccine.

A piece of DNA is placed within a harmless virus. When that virus is injected into your body, DNA enters the cell and then it is translated into the mRNA and the mRNA then makes the spike protein. The spike protein then induces an immune response.

Viral vector vaccines have been around since the 1970s. They have recently been used to combat the Ebola outbreaks in Africa, and have been studied for use on other diseases like Zika, flu, and HIV.

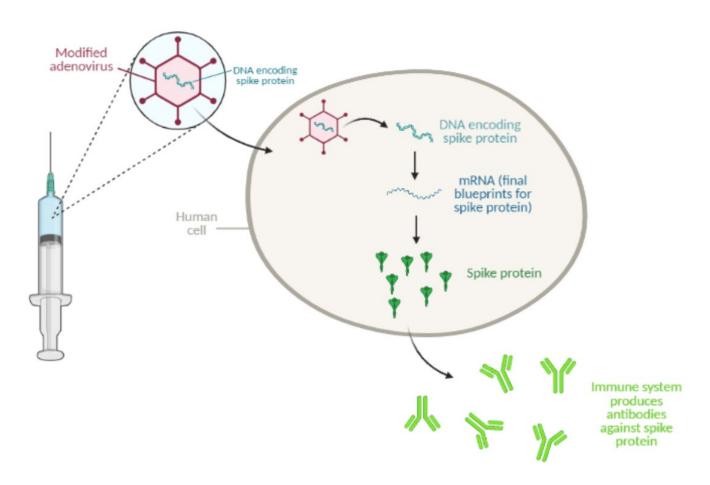


Image made using biorender.com

- The DNA code for the spike protein is cut and placed into a virus
- The DNA enters the cell, is translated into mRNA, the mRNA makes the protein
- The body reacts to the protein and leaves antibodies that are ready to respond to the COVID-19 virus

(https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/viralvector.html)



What are the ingredients in the COVID-19 vaccines?

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
Active ingredient	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication- incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
ingredients	2[(polyethylene glycol (PEG))-2000]-N,N- ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl- rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3- phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2- hydroxyethyl) (6-oxo-6- (undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

Credit: CDC

These vaccines do not contain any aluminum or thimerosal. They also do not contain any tracking chips.

What are the side effects of the COVID-19 vaccines?

The most common side effects are:

Sore arm, fever, cold sweats, dizziness, and weakness which lasts 24-48 hours.

If you have a response to the vaccine, it means that it is working properly and preparing your body to fight the COVID-19 virus.

What are the risks of a COVID-19 infection on children in the disability population?



In assessing pediatric patients tested for COVID, Black, Hispanic, or Asian children were less likely to be tested but more likely to have a positive test result when tested. This report also indicated that those with Types 1 and 2 diabetes, malignant disorders, gastrointestinal disorders, genetic disorders, hematologic disorders, musculoskeletal disorders, mental health disorders, and metabolic disorders were more likely to have a positive test result. Severe illness was seen in 7% of the cases that tested positive, and the fatality rate was 0.2% (Bailey, C. 2021).

Another study found that 25% of children who were admitted to the hospital with COVID-19 were obese. They also found that 80% of the critically ill children from COVID-19 were medically complex and already had long-term underlying medical conditions (Shekerdemian, L 2020). Another study reviewed the medical history of 48 of 108 pediatric patients who required ventilation and found that 75% of those children had documented comorbidities, of which 23% had pre-existing cardiac disease (Williams, N 2021). Researchers studied the hospitalization rates of children during March 2020- January 2021 and found that 62.9% of children hospitalized had an underlying medical condition. (Kompanlyets, L 2021)

What are the risks of a COVID-19 infection on adults in the disability population?

People with intellectual disabilities are at greater risk of contracting COVID-19 and have a higher risk of mortality from COVID-19 compared to the general population (Gleason, J 2021). A whole nation study of Scotland found that adults with intellectual disabilities were twice as likely to get COVID-19, and 2.5 times more likely to die from it. (Henderson, A 2021). Another study showed that people with disabilities who lived in group home settings in New York during the first wave of the pandemic had a 15% case-fatality rate compared to a 7.9% rate for the entire state (Landes, S 2020). People with Down syndrome were also found to have a 4-fold increase in hospitalization and a 10-fold increased risk of death from COVID-19 (Clift, A 2020). In another study that looked at the whole population of England found that those with chronic disease and those who had learning disabilities had a higher odds of mortality, with the exception of diabetes and hypertension (Joy, M 2020).

Why is this population at greater risk? Many in this community have comorbidities which makes it more difficult to fight the virus. Many in this community also rely on other people to assist in their basic activities for daily living which means they can not quarantine as well as the general population. Others with severe mental illness are not aware of the ongoing pandemic, and many with severe illness (75%) did not report fearing contracting the virus (Kamalakanna, S 2021).



If the risk of death is only 1-2% why is getting the vaccine so important?

The survival rate for COVID-19 is around 99-98% but many who get COVID end up with long-term side effects that affect their overall health and wellbeing. Long- COVID describes people who still have symptoms from COVID 2-3 weeks after they were initially diagnosed.

One study found that two months after symptom onset, 66% of patients presented at least one symptom, 30% reported labored breathing and 40% reported physical weakness and lack of energy (Carvalho-Schneider 2020, Stavem 2020). COVID-19 not only affects the lungs but brain function as well. In a study looking at patients who had mild-to-severe COVID-19, 58% of patients had decreased mental function and 39% had major depression (Mendez 2021).

Do children get long-COVID symptoms?

Long term studies in children have found that 76% of all children who were diagnosed with COVID-19 have persistent symptoms 6 months after initial diagnosis. "Insomnia (18.6%), respiratory symptoms (including pain and chest tightness) (14.7%), nasal congestion (12.4%), fatigue (10.8%), muscle (10.1%) and joint pain (6.9%), and concentration difficulties (10.1%) were the most frequently reported symptoms." (Buonsenso 2021)

Another study looking at 90 children who had long-COVID symptoms reported that 58% of had an impairment in daily activities due to symptoms. They reported fatigue (71%), difficulty breathing (50%) and muscle pain (45%) (Ashkenazi-Hoffneng 2021).

What can you do if your child is too young to get the vaccine?

If your child is still too young to get the vaccine it is important that you create a layer of protection around them by getting vaccinated, and ensuring that therapists who work with them are also vaccinated.

You should still have them wear masks when they are out in public. Child mortality from COVID-19 is extremely rare, but we are still unsure of how COVID-19 affects people long-term. To be safe, mask up.

What are variants and how do the vaccines react to the variants?



Viruses can change as they move from one person to another. The original strain is called the Alpha strain and as the virus mutates different strains are given different names. This can result in different variations (variants) of the virus. The changes can either have little or no effect or cause the virus to transmit easier and cause more serious infections.

As of July 30th, 2021, the Delta variant has been found in 83% of cases in the United States. This variant is 60% more transmissible than the original strain and has a viral load 1,000 times higher than the original strain.

On November 25, 2021 the Omicron variant was detected in South Africa. It was first detected in the United States in December and quickly became the dominant variant. Omicron variant was found to be more contagious than Delta but less deadly.

As of this publication, two variants have swept through the world: Delta and Omicron. In both cases the vaccines were still shown to decrease the likelihood of hospitalization and death, although more breakthrough infections were seen with the Omicron variant.

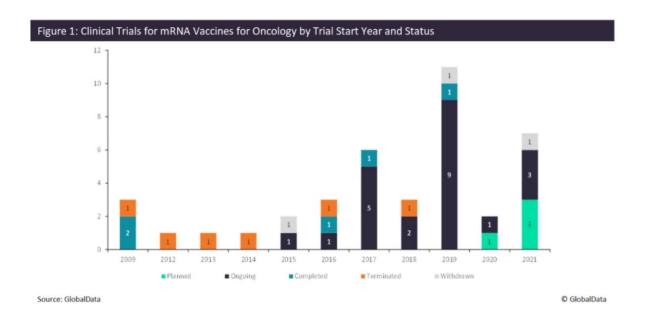
What are breakthrough cases?

Breakthrough cases occur when vaccinated people become infected with COVID-19. The vaccines for COVID-19 are very effective in preventing hospitalizations and death but they are not 100% effective. For example, if a vaccine has a 95% efficacy rate, then 5% of people who get vaccinated can still become infected with the virus they were vaccinated against.



Long-term effects of mRNA vaccines

Many have expressed an interest in learning about the long-term side effects of mRNA vaccines. mRNA vaccines have been tested on humans since 2009 in various clinical trials.



mRNA breaks up rapidly in the body and so usually any side effects that would present themselves would do so early on. To date, only a few long term side effects have been linked to the mRNA vaccines and reported to the VAERS system. The most widely reported was myocarditis or pericarditis in teen and young adults, this lead to hospitalization of some, but zero deaths.

What is VAERS (Vaccine Adverse Event Reporting System)?

This is a self-reporting system in place to keep track of possible side effects from the vaccine. Have there been reports to VAERS after vaccination of the COVID-19 vaccines? Yes, there have been. When scientists look at the data collected in VAERS, they are looking to make sure that the vaccine is what CAUSED the adverse side effect being reported.

For example, in June 24, 2021, the <u>FDA</u> put out a warning about the risk of myocarditis or pericarditis as a side effect of the mRNA vaccine. They reported finding 323 established cases. Think about that for a minute. Think about what 323 people represents in terms of scale. In June 2021, the US had administered <u>309 million vaccinations</u>. The alert they put out affected 0.0001% of the people who were vaccinated.

They are closely monitoring this vaccine and side effects that are reported into the VAERS system. When they find that a symptom is being caused by the mRNA vaccine, they are reporting it.

If I had COVID, do I need to be vaccinated?



When you get COVID, your body does produce an immune response that does protect you from further infection for a while. Studies have shown that this protection fades over time. After 7.7 months your body has lost most of its antibodies and you are no longer protected from getting infected by COVID (Ortega, Natalia 2021).

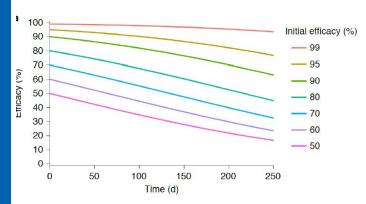
If you were diagnosed with COVID 8 months ago or longer, you should get vaccinated.

If I already got the vaccine, will I need a booster shot?

Yes. On August 18, 2021, the CDC stated that a booster shot will be needed for the mRNA vaccine. Just like your protection decreases over time if you were infected with COVID, your protection also declines over time if you received the mRNA vaccination. Studies show that a booster is needed 8 months after patients have had their second shot. In September, the FDA authorized a Pfizer-BioNTech booster shot for people 65 and up, long-term care residents, and anyone 50-64 with an underlying health condition.

Why are booster shots needed?

Like most vaccines, the protection given to the patient wanes over time. Therefore, booster shots are required.



- Vaccine starting with initial efficacy of 95% expected to maintain high efficacy (77%) after 250 days
- Vaccine starting with initial efficacy of 70% may result in drop to lower efficacy (33%) after 250 days

Khoury, David et al. 2021

These vaccines were designed to protect us against the original Alpha strain not from Delta, and so they are not as effective now with the new variant. Given that, and the fact that our protection decreases over time, Delta is more likely to cause breakthrough infections as time goes on.

New clinical trials are ongoing to give booster shots that target the Delta variant and have shown a promising immune response (Kai Wu, 2021).



Who can get a booster?

Anyone ages 12 years and older can get a Pfizer-BioNTech booster shot.

If you received	Who should get a booster	When to get a booster	Which booster should you get?
Pfizer-BioNTech	Everyone 12 years and older	At least 5 months after completing your primary COVID-19 vaccination series	Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most* situations Teens 12–17 years old may only get a Pfizer-BioNTech COVID-19 vaccine booster
Moderna	Adults 18 years and older	At least 5 months after completing your primary COVID-19 series	Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most* situations
Johnson & Johnson	Adults 18 years and older	At least 2 months after receiving your J&J COVID-19 vaccination	Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most* situations

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

How have vaccines impacted people in Arizona?



In November, unvaccinated persons had:

4.9X	17.5X	31.1X
Risk of Testing Positive for COVID-19	Risk of Hospitalization from COVID-19	Risk of Dying from COVID-19

compared to fully vaccinated persons.

How can you have a good vaccination experience?

A great place to start is with this Guide for Caregivers.

Links to videos:

Let's Talk about the Corona virus: UMNSU CARD

Facts about the COVID-19 vaccine: <u>Autistic Self Advocacy Network</u>

Accessible video for people with learning disabilities: Hft Learning Disabilities

COVID-19 Vaccines and People with Disabilities: DDI at WSU

Links to social stories:

Getting a COVID-19 vaccine: Rutgers

Getting a Vaccine: <u>Howard County Autism Society</u>

How I get my COVID-19 shot- CDC

Talk to your doctor.

We understand that this document may not have answered all of the questions you have about the vaccine. If you are still concerned about the vaccine please talk to your doctor. You might want specific information regarding the risks and benefits of getting your child vaccinated when taking into account their disability. If your child has seizures, you might want to ask about the possibility of a fever induced seizure after your child gets the vaccine and what steps you can take to prevent that from happening.



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